Applicant:	Jeppesen.	Examiner:	A. Bunin
Serial No:	10/629,511	Art Unit:	3743
Filed:	August 12, 2004		

Title: Method and Apparatus for Treating Obstructive Sleep Apnea Syndrome

DECLARATION OF DR. JOHN JEPPESEN RULE 1.132

I, Dr. John Jeppesen, declare and state:

1. I am the Applicant for the pending U.S. application no. 10/629,511 entitled "Method and Apparatus for Treating Obstructive Sleep Apnea Syndrome".

2. I graduated with a B.S. in Biology from California Lutheran College (1978). I received a D.M.D. (Doctor of Dental Medicine) from Fairleigh Dickinson University in 1982. I passed the California Dental Board in July of 1983. I have been in private practice subsequent to passing the board exam. In 1996, I began taking continuing education courses in the area of sleep medicine. Since early 2000, my practice has essentially been limited to the treatment of sleep-disordered breathing patients. I was a member of the Academy of Dental Sleep Medicine from 2000-2003. I have taken numerous continuing education courses in the area of sleep medicine.

3. In regard to the Goldstein patents U.S. Pat. No. 5,752,510 and 6,012,455, my comments are as follows. The mouthpiece or dental anchor presented in Goldstein is not capable of addressing the significant variations in oral anatomy of humans. There is no way to customize the required fit unless the presenting anatomy happens to coincidentally match the arch form of the device. From a clinical perspective, this lack of customization

is problematic and routinely fails to produce a positive outcome for patients that I have seen.

4. As a specialist provider, I know many board-certified sleep physicians. I am unaware of even one physician specializing in sleep apnea therapy who has ever recommended any of their most difficult-to-treat sleep apnea cases for therapy with the products patented by Goldstein even though these physicians are well aware of the Goldstein device.

5. In Goldstein '510, his original patent, he discloses that the mandibular arch component in his "dual arch" design was to "protrude the mandible to clear the airway passages." Protrusion of the mandible can be helpful but also problematic. Protruding the mandible can mechanically dilate the upper airway. To the best of my knowledge, a mandibular advancement device (MAD) is used by more than 99% of all dentists who treat obstructive sleep apnea patients. Mandibular advancement or protrusion of the mandible is by far the most dominant method of treating the OSA patient who utilizes an oral appliances in lieu of nasal CPAP. The only other type of oral appliance utilized occasionally by such specialists would be the tongue retention device (TRD). There are many variations of MADs and some variations of the TRD approach, but all these methods rely on some form of mechanical manipulation of the soft tissues to dilate the upper airway and/or prevent the collapse of the tongue posteriorly at night. In regard to Goldstein's lower arch component, if the most anterior surface of the mandibular component of the dual arch design prevents the mandible from reaching the therapeutic (protruded) position because it limits the range of protrusion due to the fact that his lower arch is premade in a fixed position, then the mandibular component is of zero value.

6. In my experience, advancing the mandible is a two-edged sword. It can help to correct obstructive sleep apnea (OSA), but it can also cause a host of problems including but not limited to tooth soreness, loosening of teeth, sore muscles, temporal mandibular joint (TMJ) dysfunction, loss of teeth, significant changes in dental occlusion, and osseous remodeling of the mandible resulting in permanent advancement of the mandible.

7. The Goldstein patents are silent regarding any need for obturation of the oral cavity. Likewise, there is no mention of using the lower arch component to stabilize the position of the mandible to prevent its collapse posteriorly at night or to create a pneumatic seal referred to in my specification as obturation of the oral cavity. However, Goldstein '510 does indicate the need for a "chin stabilizer." If the mandible drops open at night while the nasal passages are pressurized, air will escape. In this scenario, some sort of chin stabilizer can help to prevent this event from occurring but Goldstein '510 discloses holes 29 in mouthpiece 25 thereby encouraging airflow out of the oral cavity. Therefore, Goldstein '510 does not use its mouthpiece to obturate the oral cavity.

8. Goldstein's art does not speak to any particular concept of mandibular positioning except advancing or protruding the mandible although the more recent Goldstein '455 discloses a dental anchor but is silent with respect to neutral centric positioning and obturation. This is not unusual because essentially all sleep apnea oral appliance therapists, except for myself, routinely advance the mandible to mechanically dilate the upper airway. Even I followed this procedure routinely for many years. I continued to advance mandibles routinely until I realized that in most cases it was an unnecessary risk for the patient so long as I could create excellent pneumatic seals at the nares and the oral cavity. In this scenario, the pressurized air would be forced down into

the hypopharynx which ultimately created a pneumatic splint without any mechanical dilation of the airway.

9. It took me treating many patients with custom continuous positive airway pressure (CPAP) interfaces to understand this very subtle but novel concept: that mechanical dilation of the upper airway presented more risk to the patient than it was worth. Clinical follow up with some of my mandibular advancement cases showed clear detrimental occlusal changes produced by these MAD devices. I observed proclination of lower anterior teeth and retroinclincation of upper anterior teeth. I saw significant changes in the plane of occlusion including both extrusion and intrusion of molar and premolar teeth which resulted in change in vertical dimension of occlusion. I observed permanent advancement of the mandible of 2-7 mm.

10. When the mandible becomes permanently advanced significantly, a patient's dental occlusion can become virtually destroyed. This extreme change in occlusion prevents patients from masticating their food properly and can cause gastro-intestinal problems such as incomplete physiologic absorption of nutrients. Permanent advancement of the mandible also will subsequently result in fracture of teeth causing either the need for extensive repair via crown placement and/or root canals or outright loss of the injured tooth requiring extraction and prosthetic replacement. Permanent advancement of the mandible may require extensive orthodontic treatment and/or orthognathic surgery to correct. Orthognathic surgery carries with it all the concomitant risks of any major surgical procedure including but not limited to risk of death under general anesthesia or possibly permanent parasthesia (numbness due to nerve damage). MADs also can cause serious injury to the tempor-mandibular joint resulting in all sorts

of pathology such as muscle spasm, disk displacement, pain, stiffness, and migraine headaches.

11. In June of 2003, I attended the annual meeting of the Academy of Dental Sleep Medicine. The last speaker at this conference was Dr. Alan Lowe who is a professor in the orthodontic department at the University of British Columbia. Dr. Lowe presented the very first preliminary data which documented these observations stated above scientifically. Even though the data was preliminary, the estimated risk for (mandibular) Class I occlusions was severe enough that routine, arbitrary advancement of the mandible, in my opinion, needed to be avoided as often as possible. It was at this time, in early June of 2003, that I became more convinced that another method besides mandibular advancement was necessary to treat chronic sleep apnea. It was at this time that a neutral centric position for treatment of sleep apnea made the most sense both orthopedically and orthodontically.

12. When the mandible is placed within the zone of the neutral centric position, the orthopedic health of the TMJs are maximized, orthodontic, deleterious changes are minimized, and nocturnal parafunction is almost completely erased in my observation. In this case, the remaining issue revolves around optimal pneumatics when switching the patient's treatment plan to the use of positive airway pressure. By positioning the mandible in a neutral centric position within the dual arch oral appliance, the patient's tongue is most often placed in the best position to create an oropharyngeal-lingual seal. It is my observation that the neutral centric position not only protects hard and soft tissues from injury, but this position also significantly assists in obturating the oral cavity itself. The creation of excellent pneumatic seals is likely why my rate of

positive outcome is so unusually high with documented failures of standard nasal CPAP therapy cases.

13. As a neuromuscular dentist, I am familiar with the concept of neutral centric position. There is a specific procedure and protocol that must be adhered to in order to locate this specific position. Finding this neutral centric position requires the use of some method to profoundly relax the muscles of mastication which postures the mandible. The mandible is not a hinge joint like on a puppet. The temporo-mandibular joint allows the mandible to move like an airplane with pitch, yaw, and roll. It is therefore not possible for a standard mouthpiece to be used which will predictably provide patients with a neutral centric position. Dental impressions and a separate bite registration which captures the neutral centric position are required from each patient; neither of which are discussed by either the Thornton or Goldstein references. The method that I use to build these custom nasal CPAP interfaces is both technique and labor intensive. I first take preliminary impressions of the upper and lower dental arches using irreversible hydrocolloid (alginate) impression material. From these impressions preliminary casts are poured. The preliminary casts are then utilized to create custom impression trays. These custom impression trays are then filled with polysiloxan impression material which is more accurate than the alginate material. These impressions are then poured to create master casts. Next, a neuro-muscular tens bite registration is created. By applying a low-frequency pulsing to the masticatory muscles, the mandibular complex positions itself into the neutral centric position. Once the engram has been erased and the muscles profoundly relaxed, the patient is instructed to slowly close into a bite registration material until the appropriate vertical dimension is established. From

here, the registration material sets and is used to mount the master casts in the neutral centric position. Neither Goldstein nor Thornton utilize this methodology. Without using this type of approach it is simply not possible to capture the neutral centric position for fabrication of the orthotic. There must be no interference between the dental arches during the bite registration procedure. I do not even allow the patient to swallow during this bite registration procedure as one contact between the teeth during a swallowing event will create a new (undesirable) engram. Again, one purpose of this procedure is to erase any previous engram.

14. The temporo-mandibular joint has specific movement or trajectory. The trajectory is based on a complicated neural feedback mechanism referred to as an "engram." The engram is similar to a computer program for guiding the complex movement of the mandible. Most dental occlusions are not sound orthopedically; rather they are acquired and acclimated to by the patient. The use of Transcutaneous Electrical Nerve Stimulation (TENS) is a preferred method for producing the profound muscular relaxation and locating the neutral centric position. But, the TENS procedure also performs one other very important function. It produces "erasure" of the current engram which has been acquired and is unsound orthopedically for the vast majority of patients. When treating a patient with a dual arch appliance at night, it is essential that the mandible be positioned in an orthopedically preferred position to prevent discomfort and possible onset of pathology. The preferred position to achieve both outcomes would be the neutral centric position.

15. Another function of my dual arch approach and mouth venting is to prevent mouth breathing during treatment with positive airway pressure. Obturation of

the oral cavity forces patients to inhale and exhale only through their nose. This is a key concept in producing positive outcomes. The goal is to prevent nasal breathing OSA patients from ever breathing through their mouths during therapy. I isolate the oral cavity via obturation and have them breathe nasally. I believe this concept is not obvious and is novel.

16. The Examiner has also referenced U.S. Pat. No. 6,571,798 issued to Thornton. Thornton's art truly emphasizes the concept of mandibular advancement. His orthotic is one of the best instruments for precisely dilating the upper airway mechanically since the upper and lower dental arches can be adjusted relative to one another.

17. Thornton's patent issued subsequent to the Goldstein '455. It is Goldstein '455 that discloses a dental anchor 24 in the shape of a horseshoe. Similarly, Thornton '798 also discloses upper and lower arches coupled together with a deformable material 16. However, Thornton '798 also incorporates a venting seal 24 to prevent air from exiting the oral cavity. It is submitted that since the mouthpieces presented in Goldstein '455 and Thornton '798 are similar, and Thornton '798 teaches the need for a venting seal to prevent air from exiting the oral cavity, then the dental anchor presented Goldstein '455 is not capable of substantially preventing the escape of air from the oral cavity.

18. Attached to my declaration is Exhibit A that documents 52 patients I have treated with my disclosed invention. In clinical practice, 52 patients is indicative with regard to the effectiveness and compliance of any therapy, particularly when the rates of positive outcome are unusually high.

19. Of the more than 52 patients being treated, 25 have underwent follow-up nocturnal polysomnogram examination (NPSG) to measure a patient's respiratory disturbance index (RDI). RDI is defined as the average number of respiratory disturbances observed per hour. These 25 patients were initially treated with standard therapy (i.e. not my therapy) and were considered failures by their treating physicians before being referred to me. The results indicate that 100% had positive outcomes as quantified by the Post-Treatment RDI column. I define a positive outcome as either a minimum 70% improvement over the baselinel RDI or less than 5 respiratory disturbance events per hour. It should be noted that my 70% improvement threshold for measuring success is higher than most studies of which I am aware. It should also be noted that all 25 patients originally had respiratory disturbances in the range of 8-78 events per hour without treatment.

20. In my Exhibit A, there are also 27 patients who have not participated in Post-Treatment NPSG. However, I still consider these patients to have been treated successfully through feedback received directly from the patient. According to my follow up, more than 85% of all patients that I've treated and who have failed previous apnea therapy treatments, have found improved correction of their sleep apnea. Six cases are identified in the right column as either a "no" (i.e. someone who has discontinued use); or a "N/A" (i.e. someone who I have not been able to contact for follow-up).

21. I have received my referrals from physicians who have treated OSA and work in the Southern California area. Typically, referrals come from board-certified sleep physicians, pulmonologists, otolaryngologists, internists, and family physicians who heard about my success correcting sleep apnea. Most of the physicians that

routinely refer patients to me I have never met. By and large my practice is comprised of "failures" of standard therapies be it nasal CPAP or surgeries or oral appliances.

22. Prior to my using a dual arch oral appliance for obturating the oral cavity having a neutral centric position, I am unaware of any other physician or person who used this technique for treatment of chronic sleep apnea.

The Declarant is aware that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon. All statements made of declarant's own knowledge are true and all statements made on information and belief are believed to be true.

I declare under the penalty of perjury that the foregoing is true and correct.

/John C. Jeppesen/ Dated: June 23, 2006

Dr. John C. Jeppesen.

Exhibit A Patient's having Chronic Sleep Apnea

Pt. #	Age	M/F	Baseline RDI	Post-Treatment RDI as Measured by NPSG	Use
1	49	F	22.7	N/A	yes
2	49	M	17	N/A	yes
3	73	M	34	0	yes
4	55	M	16	N/A	yes
5	63	M	48	N/A	yes
6	61	M	113	N/A	yes
7	70	M	10	1.5	yes
8	65	M	78	6	yes
9	73	M	68	3.8	yes
10	58	M	18	N/A	yes
11	67	M	37	N/A	yes
12	53	F	45.5	N/A	yes
13	53	F	7.4	N/A	yes
14	53	F	20	1	yes
15	76	M	10	0	yes
16	66	M	20.6	0.8	no
17	47	M	43	1	yes
18	49	M	51.2	N/A	yes
19	63	M	30	6	yes
20	60	F	136	N/A	N/A
21	41	M	48	N/A	yes
22	75	M	46	3.7	yes
23	43	M	73	N/A	yes
24	45	F	52.3	N/A	yes
25	66	M	17	N/A	yes
26	70	M	30	0.9	yes
27	52	M	44.5	1	yes
28	71	M	40	2.6	yes
29	59	M	20.4	N/A	yes
30	68	M	17	N/A	yes
31	50	M	8.6	N/A	yes
32	53	M	58	N/A	yes
33	63	M	62	N/A	no
34	50	M	7	N/A	yes
35	57	M	6.5	N/A	yes
36	79	F	8	0.5	yes
37	79	M	105	N/A	yes
38	44	M	30.4	N/A	yes
39	71	M	64	6.5	yes
40	50	F	26.8	N/A	N/A
41	76	M	18.8	N/A	yes
42	63	F	45.8	0	yes
43	85	M	20.5	1.7	yes

44	66	F	48	13.5	yes
45	80	M	26.1	1	yes
46	79	F	29	0	yes
47	51	M	32.3	4.6	yes
48	61	M	61	10	yes
49	39	F	20.9	5.5	N/A
50	84	M	60	3	yes
51	61	M	68.9	N/A	no
52	75	F	20	0.9	yes